IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	THENNATI ET AL.	Examiner:	RITA J. DESAI
Serial No.:	10/510,619	Group Art Unit:	1625
Filed:	OCTOBER 7, 2004	Docket No.:	15395.11USWO
Confirmation No.:	1765		
Title:	SUBSTANTIALLY PURE ANTIHISTAMINIC COMPOUND		

DECLARATION OF DR TRINADHA RAO CHITTURI UNDER 37 CFR § 1.132

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

I, Dr. Trinadha Rao Chitturi, declare and say as follows.

1 I am a citizen of India and reside at Vadodara, Gujarat, India.

2 I hold a doctorate degree in Organic Chemistry from the **Indian Institute of Technology, Kanpur**, India..

3 I presently hold the position of, Vice President, R&D, at **SUN PHARMA ADVANCED RESEARCH COMPANY, LTD.** where I am responsible for, R&D (Organic synthesis), heading a group of 29 scientists in Organic Chemistry. Over the past 14 years, I acquired proficiency in conducting Process Research and Development of complex API's, of interest to the organization and drug discovery. In particular, my experience includes work on developing novel / cost

effective processes for API's. I have been actively involved in such type of work for about 18 years. My curriculum vitae is attached as Annexure I.

4 I have read the Office Action mailed May 20, 2009 in the patent application identified above and three references cited in this office action, Fisher et al. (WO02/42290), Fountoulakis et al. (*J. Chromatography A*, 1998), and the excerpt from the Sigma-Aldrich catalog.

5 I understand that the Office Action argues that a scientist would arrive at our method of converting loratadine to desloratidine with methanesulfonic acid by combining,

a) the use of mineral acids (such as sulfuric acid, hydrochloric acid, or hydrobromic acid) to convert loratadine to desloratadine by the method of WO02/42290; and

b) the use of methanesulfonic acid for hydrolyzing proteins to their constituent amino acids by the methods of the Fountoulakis et al. reference and the excerpt from the Sigma-Aldrich catalog.

I disagree with the Office Action for the following reasons.

Converting Loratadine to Desloratadine Using Organic acids was Unpredictable

6 Our research group tested several organic acids for their ability to hydrolyze loratadine to desloratidine in high yields. A total of five organic acids were tested for this reaction, and only methanesulfonic acid was found to be useful. Three of the five organic acids - trifluoroacetic acid, trichloroacetic acid, and formic acid - were shown to be totally ineffective at converting loratadine to desloratadine.[1] One of the organic acids, *p*-toluenesulfonic acid, produced desloratadine in unacceptably poor yield.[2]

[1] 1g of loratadine was mixed with 7.6g of trichloroacetic acid and 0.5 mL of water; heated to 110°C, and refluxed for 7 hours. Very little desloratadine was detected at the end of the reaction. 10g of loratadine was mixed with 30mL of trifluoroacetic acid and 3 mL of water, and heated to 70 °C for 5 hours. No reaction was detected.

7 As shown in the examples in the patent application identified above, methanesulfonic acid converted loratadine to desloratadine at 89% yield and provided a product of 99.96% purity. Among the organic acids that we tested, only methanesulfonic acid was the most effective for converting loratadine to desloratadine.

8 These results demonstrate that it is not possible to predict that an organic acid or that any particular organic acid, such as methanesulfonic acid, would be effective for converting loratadine to desloratidine.

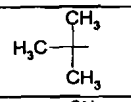
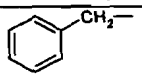
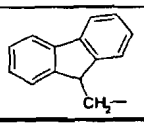
Carbamate Cleavage by Organic Acids Cannot be Generalized

9 This conditions for cleavage of different carbamates (also called urethanes) is also shown by a brief review of the scientific literature on reactions of carbamates. Converting loratadine to desloratadine involves cleavage of a carbamate group on the loratadine to yield the amine, desloratadine. When the cleavage is hydrolytic, desloratadine is produced with the liberation of carbon dioxide and ethanol.

10 If we look at the carbamate functionality **ROC(O)**NHR', its cleavage to the corresponding amine R'NH_2 can be significantly different for any given reagent depending upon the nature of R. Further, for any given R the reactivity of the carbamate could be significantly different towards different hydrolyzing/cleaving reagents. For example, take the case of the three different carbamates, wherein R represents A, B and C moieties respectively as shown below:

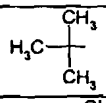
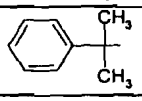
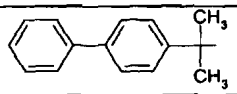
1g of loratadine was mixed with 1.75mL of formic acid and 0.14mL of water, heated to 110°C, and refluxed for 5 hours. No reaction was detected.

[2] 10g of loratadine was mixed with 30 mL of *p*-toluenesulfonic acid and 3 mL of water, and heated to 110°C for 6 hours. Some conversion to desloratadine was detected. Additional 20 g of *p*-toluenesulfonic acid was added and the heating at 110°C was continued for 10.5 hours. At the end of the reaction, the unconsumed loratadine and 1.6g of white solid (desloratadine) was recovered. This is an unacceptably poor conversion.

Type	Moiety, R	Chemical Name	Notation for the carbamate
A		*tert*-Butyl	Boc
B		Benzyloxycarbonyl	Z
C		9-Fluorenylmethyloxycarbonyl	FMoc

11 The carbamate having the moiety A is acid labile and is readily cleaved to the corresponding amine R'NH_2 under mildly acidic conditions, such as by treatment with cold trifluoroacetic acid, whereas the carbamates with moieties B & C would not react under the same conditions. Similarly, the carbamate having moiety B can undergo catalytic hydrogenolysis (using hydrogen and Pd-C catalyst) to give the corresponding amine, while carbamates with moieties A & C do not. Further, the carbamate with moiety C can be cleaved to the corresponding amine with a secondary amine such as piperidine; however carbamates with moieties A & B would remain intact (*Gross. E., Meinhoffer J., The peptides, Vol 3, Academic press; Chapter I, Sec III "The types of Amine Protecting Groups"*)

12 Besides, if we look at the relative reactivities within a particular type of carbamate, say for carbamates related to moiety A, we can find significant differences, as shown in the Table below (*Gross. E., Meinhoffer J., The peptides, Vol 3, Academic press; Chapter I, Sec III "The types of Amine Protecting Groups", pg 35*).

Type	Moiety, R	Chemical Name	Notation for the carbamate	Relative cleavage rate in 80% acetic acid
A		*tert*-Butyl	Boc	1
A		2-Phenylprop-2-yl	Poc	700
A		2-(4-Biphenyl)prop-2-yl	Bpoc	3000

13 Therefore, I conclude that cleavage/ hydrolysis of carbamates cannot be generalized. It is not possible to know beforehand the reagent that would work most suitably for the cleavage/ hydrolysis of any particular carbamate. Certainly, one cannot extrapolate the findings of protein hydrolysis to carbamate hydrolysis.

14 I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Date: August 26, 2009

Dr. Tirnadha Rao Chitturi

Curriculum Vitae'

Dr. Trinadha Rao Chitturi

Knowledge/ Skills

Chemistry

Synthetic organic chemistry, reaction mechanism, development of newer reagents and novel synthetic methodologies, data acquisition using modern techniques, structural analysis and interpretation

Medicinal chemistry/ Drug discovery

Medicinal chemistry concepts and designing of NCE's related to pharmacological targets.

Chemical drug delivery systems, designing of soft drugs and pro-drugs.

Understanding/ designing of screening protocols and interpretation of *in-vitro* and *in-vivo* data

IND filings & documentation

Process Development

Innovative & non-infringing processes – identification and development

Development of cost effective process for bulk drugs & intermediates, scale-up, technology transfer and commercialization

Custom synthesis

Documentation for filing of drug master files (DMF's)

Intellectual Property Rights

Understanding of patent laws, issues related to patentability and infringement.

Writing patent specifications for product and process patents

Leadership, Training & Managerial

Provide leadership to research team consisting of Postdoctoral fellows, Ph.D's & M.Sc's

Designing, setting-up & organization of synthesis/ medicinal chemistry labs.

Conducting seminars, interviews, organizing for symposia activities

Devising systems, SOP's, protocols etc for effective management

Delivering guest lectures and invited talks at Universities/ Institutions, workshops & conferences

Expert membership in research committees of Institutes (for Ph.D & Post graduate programs)

Academic/ Education		
Postdoctoral	1987-1991	**National Institutes of Health (NIH), Maryland USA** GRC/Macromolecular Chemistry Division, Baltimore MD21224 *Fogarty International Fellow* Post-Doctoral research under eminent scientist, Dr. Josef Pitha (Chief, Macromolecular chemistry division) in • medicinal chemistry, viz. synthesis of novel adrenergic compounds • carbohydrate chemistry viz. chemistry of cyclodextrins with emphasis on pharmaceutical applications. *Accomplishments:* • Research culminated in 9 publications in journals of international repute • A US patent on "Synthesis of specifically substituted cyclodextrins" has been granted
Ph. D	1981– 1987	**Indian Institute of Technology, Kanpur, U.P., India** Doctoral research under eminent Prof. Y. D. Vankar in the area of development of newer reagents for organic synthesis and study of reaction mechanisms. Submitted thesis entitled "Some newer aspects of Ritter reaction and development of reagents for organic synthesis" *1982-1985-Teaching Assistantship – conducted tutorial classes for undergraduate students at IIT, Kanpur* *Accomplishments:* • Secured 'A' grade in all courses during course work • Research culminated in 7 publications in journals of international repute • The research work is cited extensively, including in standard text books and reference books ("Advanced Organic Chemistry" by Jerry March, "Reagents for Organic Synthesis" by Fieser & Fieser etc)
M. Sc	1978 – 1980	**Andhra University, Visakhapatnam, A.P., India** Dept. of Chemistry Specialization in organic chemistry *Accomplishments:* Department topper in final year (92% in final semester) Distinction in M.Sc. State merit scholarship during M Sc
B. Sc	1975-1978	**Andhra University, Visakhapatnam, A.P., India** Mrs. A. V. N. College, Visakhapatnam Specialization in Chemistry, with mathematics & physics as ancillaries. Overall percentage 72%.

Employment Experience	
2007-Present	Vice President, R&D, Sun Pharma Advanced Research Company Ltd.
2006-2007	Vice President, R&D,
2004-2006	Senior General Manager, R&D
2001-2004	General Manager, R&D
2000-2001	Dy. General Manager, R&D
1998-2000	Senior manager
1996-1998	Manager grade-I
1995-1996	Manager grade-II
	Sun Pharma Advanced Research Centre (SPARC), Tndalja, Baroda *Main functions (Discovery Research & Process research)* • Design synthesize and develop new chemical entities for therapeutic applications in allergy, inflammation & cancer • Design of pro-drugs for enhancement of therapeutic index • Develop novel / cost effective processes for API's; new polymorphs & processes thereof • Provide leadership to group consisting of Post-docs, Ph.D's and M.Sc's *Significant achievements* • One new chemical entity for allergy from my group has completed phase-I trials in Germany,and is undergoing phase-II clinical trials in the USA & India. Phase III trials planned in 2010 • Several new chemical entities synthesized for inflammation are in advanced stage of pre-clinical development • Filed over 30 patents including 4 patents for new chemical entities • Processes developed for more than 50 API's and have been commercialized • Non-infringing processes developed for several API's & DMF's filed
1994-1995	**Group Leader (MS-grade-IIA)**
1991-1994	Group Leader (MS-grade-IIB)
	Chemistry Research & Development, Glaxo India Ltd, 2nd Pokhran Road, Thane, Mumbai Main functions: • Develop cost effective processes API's • Custom synthesis for Glaxo, UK & Glaxo, France • Provide leadership to group consisting mainly of M.Sc's *Significant achievements* • Several cost saving technologies/ methods have been developed • Novel methodologies developed for some steroidal products • Provided several custom synthesized chemical entities for Glaxo Group
1987-1991	**Visiting fellow at NIH (Fogarty international postdoctoral fellow at the National Institutes of Health (NIH), Maryland USA** GRC/Macromolecular Chemistry Division *Fogarty International Fellow* Post-Doctoral research under eminent scientist, Dr. Josef Pitha (Ex-Chief, Macromolecular chemistry division), in • medicinal chemistry, viz. synthesis of novel beta-adrenoceptor agonists • carbohydrate chemistry viz .in chemistry of cyclodextrins with emphasis on pharmaceutical applications. *Accomplishments:* • Research culminated in 9 publications in journals of international repute • A US patent on "Synthesis of specifically substituted cyclodextrins" has been granted
1985-1987	**Class I Officer (Chemistry Divn.), Oil & Natural Gas Commission (ONGC)** KG-Project, Chennai/ Rajahmundry Selected based on all India merit through recruitment examination Main functions: • Monitoring and control of drilling fluid parameters for exploratory oil wells

Training / workshops	
2007	Workshop on leadership & Assertiveness, Indian Institute of Management (IIM), Indore, Dec 2007.
2002	Summer School in Medicinal Chemistry, Drew University, USA, July 2002.
1999	International Workshop on Combinatorial Chemistry, IICT, Hyderabad
1996	Workshop on Project Management, Indian Institute of Management (IIM), Ahmedabad, July 1996.

Invited lectures delivered at

- Invited lecture " CML, BCR-ABL & Imatinib" at Institute of Pharrmacy, Nirma University of Science & Technology, Ahmedabad, March19, 2008
- Conference on "Drug Discovery Technology-Anti Inflammatory & Pain Management", Organized by International Business Conferences at J.W.Marriott , Mumbai 29th – 30th August, 2007
- Workshop on "Drug Discovery – Recent Trends", PERD centre, Ahmedabad on August 19, 2006
- Guest lecture " Combinatorial Chemistry- What, Why & How" at SK College of Pharmacy, Mehsana
- Workshop on "Challenges in the Development of Novel Therapeutics", PERD Centre, Ahmedabad on October 12, 2003.
- Workshop on "Organic Synthesis for New Drug Discovery", PERD Centre, Ahmedabad on November 18, 2000.
- Invited lecture for Science Day at Applied Chemistry Dept., MS University, Baroda

Memberships

- Member American Chemical Society
- Life member of Chemical Research Society of India
- Expert member, Research Progress Committee, Nirma University, Ahmedabad

Research Publications

1	Characterization of Antiinflammatory Properties and Evidence for No Sedation Liability for the Novel Antihistamine SUN-1334H: Mandhane, S N, Jigar H Shah, Prashant Bahekar, Sameer Mehetre, Chandrashekhar Pawar, Ashish Bagad, Gajanan U. Chidrewar, Chitturi Trinadha Rao, T. Rajamannar; ***International Archives of Allergy and Immunology*** 2010;151:56–69
2	Preclinical efficacy and safety studies of sun-1334H, a potent orally active antihistamine agent: Mandhane, S., Ayer, Upendra B., Midha, Ajay S., Rao, C. T, and Rajamannar, T., ***Drugs in R&D,*** 9(2), 83-102 (2008).
3	Distribution of substituents in carboxymethyl ethers of cyclomaltoheptaose: Reuben. J., Rao, C.T., and Pitha, J., ***Carbohydr. Res.***, 258, 281-285 (1994).
4	Crystal structure of 6-*O*-[(R)-2-hydroxypropyl]cyclomaltoheptaose and 6-O- [(S)-2-hydroxypropyl]cyclomaltoheptaose: Harata, K., Rao, C.T., and Pitha, J., ***Carbohydr. Res.***, 247, 83, (1993).
5	Distribution of substituents in *O*-(2-hydroxypropyl) derivatives of cyclomalto-oligosaccharides (cyclodextrins): influence of increasing substitution, of the base used in preparation, and the macrocycle size: Rao, C.T., and Pitha, J., Lindberg, B., and Lindberg, J., ***Carbohydr. Res.***, 223, 99-107, (1992).
6	Synthesis of some 2-*O*-(2-hydroxyalkyl) and 2-O-(2,3-dihydroxyalkyl) derivatives of cyclomaltoheptaose: Lindberg,B., Lindberg, J., Pitha, J., and Rao, C.T., ***Carbohydr. Res.***, 222, 113-119, (1991).
7	Reactivities at *O*-2, *O*-3 and *O*-6 positions of cycloamyloses in Hakamori methylation: Rao, C. T., Pitha, J., ***Carbohydr. Res.***, 220, 203-213, (1991).

8	Substitution in beta-cyclodextrin directed by basicity: Preparation of 2-*O* and 6-*O*-[(R) and (S)-2-hydroxypropyl] derivatives: Rao, C. T., Lindberg,B., Lindberg, J., and Pitha, J., ***J. Org. Chem.***, 56(3), 1327, (1991).
9	Crystal structure of 2-*O*-[(S)-2-hydroxypropyl]cyclomaltoheptaose: Harata, K., Rao, C.T., Pitha, J., Fukunaga, K., and Uekama, K., ***Carbohydr. Res.***, 222, 3745, (1991).
10	Pharmaceutical usefulness of hydroxypropylcyclodextrins: "E pluribus unum" is an essential feature. Rao, C. T., Fales, H. M., and Pitha, J., ***Pharmaceut. Res.***, 7(6), 612, (1990).
11	Distribution of substituents in 2-hydroxypropyl ethers of cyclomaltoheptaose: Pitha, J., Rao, C.T., Lindberg, B., and Seffers, P., ***Carbohydr. Res.***, 200, 429, (1990).
12	Ritter reaction on cycloproyl ketone and cyclopropyl carbinols: Synthesis of N-acyl ketones and N-acyl homoallyamines: Vankar, Y. D., Kumaravel, G., and Rao, C.T., ***Synthetic Commun.***, 11&12(19), 2181, (1989).
13	Regioselective reductions of 2,3-epoxyacetals with zinc-chlorotrimethylsilane and lithium aluminum hydride: Convenient synthesis of 1,2 and 1,3-diones: Vankar, Y. D., Chaudhuri, N. C., and Rao, C.T., ***Tetrahedron Lett.***, 28(5), 551, (1987).
14	Sodium iodide-chlorotrimethylsilane (or boron trifluoroetherate) and zinc-chlorotrimethylsilane: Mild reagent systems for the conversion of ene-diones to 1,4-diketones: Vankar, Y. D., Kumaravel, G., Mukerjee, N., and Rao, C.T., ***Synthetic Commun.***, 12(2), 181, (1987).
15	Selective cleavage of benzyl ethers using sodium iodide-boron trifluoride etherate system: Vankar, Y.D., and Rao, C.T., ***J. Chem. Res.***, 232, (1985).
16	Reaction of sulfoxides and nitriles in presence of trifluoroacetic anhydride and trifluoroacetic acid: A case of Ritter reaction on Pummerer intermediate: Vankar, Y.D., and Rao, C.T., ***Tetrahedron***, 41, 3405, (1985).
17	Sodium iodide-boron trifluoride etherate: A mild reagent for the conversion of allylic and benzylic alcohols to iodides and sulfoxides to sulfides: Vankar, Y. D., and Rao, C.T., ***Tetrahedron Lett.***, 26(22), 2727, (1985).
18	Zinc-chlorotrimethylsilane: A mild and efficient reagent for the reduction of epoxides to alcohols: Vankar, Y. D., Arya, P. S., and Rao, C.T., ***Synthetic Commun.***, 13(10), 869, (1983).

Patents/ Inventions

1	Synthesis of specifically substituted cyclodextrins: **US Patent 5,173,481 (1992)**; Dr. Josef Pitha, Dr. C. Trinadha Rao & Prof. Bengt Lindberg
2	An improved process for the preparation of 1-(2,3-Epoxypropyl)-5-Nitroimidazoles: **Indian Pat. IN 181460 (597/ BOM/ 96)**; Dr C Trinadha Rao, Dr T Rajamannar, Dr PVR Acharyulu, Dr R Rehani and Dr N J de Souza
3	A process for the recovery of tramadol as *cis*-tramadol hydrochloride in asymptotically quantitative amounts from mixtures of diastereomers of tramadol: **Indian Pat. IN 182116 (12/MUM/2000)**; Dr T Rajamannar, Dr C Trinadha Rao, Dr Sonny Sebastian & Dr N J de Souza
4	A simple and efficient process for the preparation of fluvoxamine maleate: **US Patent 6,433,225 (2002);** Dr C Trinadha Rao and Dr T Rajamannar, Dr. K. J. Jadav, and Mr.Hemant Shah
5	A process for converting stereoisomers of sertraline into sertraline: **WO 0149638 (2001), US 6,504,940 (2003);** Dr. K. J. Jadav, Dr C Trinadha Rao and Dr T Rajamannar
6	Process for the preparation of a polymorph of 4-(Aryl-3,4-dihydro-1(2H)-naphthaleneamine derivative: **WO 0172684 (2001), US Pt. Appln.2003143906;** Dr C Trinadha Rao, and Dr T Rajamannar
7	Novel process for the preparation of 5-(3,5-dimethylphenoxy)methyl-2-oxazolidinone: **Indian Pat. 27/MUM/ 2002** (complete specs. filed 29th Nov., 2002), **WO03061552; US Pat. Appln. 20050075505;** Mr. Biren Gandhi, Mr. Samir Shah, Dr. Dr C Trinadha Rao and Dr T Rajamannar
8	4-(Diarylmethyl)-1-piperazinyl derivatives: **Indian Pat. Appln. 302/MUM/ 2002,** (provisional filed 27/03/02); **US Pat. Appln. 20050107393;** Mr. Ajay Midha, Mr. Hemant Chokshi, Dr C Trinadha Rao and Dr T Rajamannar
9	Antihistaminic compounds: **Indian Pat. Appln. 332/MUM/ 2002,** (provisional filed 8/04/02), **WO 2003/087059;** Ms. Isha Bhatt, Dr. Ranjan Pal, Dr. B. Samantha, Dr C Trinadha Rao and Dr T Rajamannar
10	Substantially pure desloratadine: **Indian Pat. Appln. 348/MUM/ 2002** (provisional filed 15th April, 2002); **US Pat. Appln. 20060058334;** Dr. K. J. Jadav, Dr. Dr C Trinadha Rao and Dr T Rajamannar
11	Process for the preparation of S-fluoromethyl-6alfa-9alfa-difluoro-11beta-hydroxy-16alfa-methyl-17alfa-propionyloxy-3-oxoandrosta-1,4-diene-17beta-carbothioate: **Indian Pat. 544/MUM/ 2002** (filed 10/06/02); **WO 2004/001369);** Mr. K. Sudhakar, K., Dr C Trinadha Rao and Dr T Rajamannar
12	Preparation of 3-[2-[4-(6-fluoro-1, 2-benzisoxazol-3-yl)-1-piperidinyl] ethyl]-6,7,8,9-tetrahydro-2-methyl-4*H*-pyrido [1,2,-a] pyrimidin-4-one: **Indian Pat. 239/MUM/2003** (Provisioanl filed on 03/03/03); Dr. K. J. Jadav, Dr. Dr C Trinadha Rao and Dr T Rajamannar
13	Process for the preparation of (1S, 4S)-4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-*N*-methyl-1-naphthylamine: **Indian Pat. 267/MUM/2003** (complete filed on 8th Aug 2003); **WO 2004/087732**; Dr. K. J. Jadav, Mr. Vijay Patel, Dr. Dr C Trinadha Rao and Dr T Rajamannar

14	Convenient synthesis of s-fluoromethyl 6α,9α-difluoro-11α-hydroxy-16α-methyl-17α-propionyloxy -3-oxoandrosta-1,4-diene-17□-carbothioate: **Indian Pat. 387/MUM/2003** (Provisional filed on 17/4/2003); **US Pat. 7,208,613;** Dr. K. J. Jadav, Dr. Dr C Trinadha Rao and Dr T Rajamannar
15	New, stable and pharmaceutically suitable crystal form IV of 2-butyl-4-chloro-1-[[2'-(1h-tetrazol-5-yl)[1,1'-biphenyl]-4-yl]methyl]-1h-imidazole-5-methanol monopotassium salt: **Indian Pat. 388/MUM/2003** (Provisional filed on 17/4/2003); Dr. K. J. Jadav, Dr. Dr C Trinadha Rao and Dr T Rajamannar
16	A process for preparation of bisphosphonic acid compounds: **Indian Pat. 837/MUM/2003** (Provisional filed on 21/08/03); **WO 2005/044831; US Pat. Appln, 20060293524**; Mr. Vijay Patel, Dr. Dr C Trinadha Rao and Dr T Rajamannar
17	Acetalization process for preparation of steroid compounds: **Indian Pat. 810/MUM/2003** (Provisional filed on 14/08/03); **WO 2005/044759;** Dr. K. J. Jadav, Dr. Dr C Trinadha Rao and Dr T Rajamannar
18	A process for preparation of [2-[4-[(4-chlorophenyl) phenylmethyl]-1-piperazinyl]ethoxy]acetic acid hydrochloride: Indian Pat 1034/ MUM/ 2003 (Provisional filed on 13/10/03); Mr. Vijay Patel, Dr. Dr C Trinadha Rao and Dr T Rajamannar
19	Process for the preparation of 2-(1-imidazolyl)-1-hydroxy-1,1-(bis)phosphonic acid : **Indian Pat 1094/ MUM/ 2003** (provisional filed 17/ 10/ 2003); **WO 2005/066188**; Mr. Vijay Patel, Dr. Dr C Trinadha Rao and Dr T Rajamannar
20	A process for preparation of antiandrogen compound: **Indian Pat. 465/MUM/2005** (complete filed on April 15, 05);). PCT Int. Appl. (2007), **WO 2007/013094**; Mr. K. Bhorkataria, Dr. K. J. Jadav, Dr C Trinadha Rao and Dr T Rajamannar
21	A process for the preparation of (-)-*trans*-4-(4-fluorophenyl)-3-[[3,4-(methylenedioxy)phenoxy]methyl]piperidine **Indian Pat. 506/MUM/2005** (complete filed on April 25, 05); **WO 2007/015262**; Ms. Mandakini Pillai, Mr. Vijay Patel, Dr. Dr C Trinadha Rao and Dr T Rajamannar
22	A process for the preparation of substantially pure 1,2,3,4–tetrahydroisoquinoline-3-carboxylic acid derivatives **Indian Pat.** (provisional filed on September 28, 05); **WO 2007/069268**; Mr. Rajesh L Giri, Mr. K. Sudhakar , Dr C Trinadha Rao and Dr T Rajamannar
23	Novel 11β-hydroxyandrosta-4-ene-3-ones : **Indian Pat.** (provisional filed on January 24, 06); **WO 2007/099548**; Dr. J. Patel, Mr. G. Sheth, Mr. G.C. Patel, Mr. S. R. Shah, Dr. S. Mandhane, Dr C Trinadha Rao and Dr T Rajamannar
24	A process for the preparation of 17α-(alkyl carbonate) derivative of 11β,17,21-trihydroxypregna-4-ene-3-one; **Indian Pat. 726/MUM/2006** (provisional filed on May 09, 06) Ms. Mandakini Pillai, Ankur Mistry, Mr. Vijay Patel, Dr. Dr C Trinadha Rao and Dr T Rajamannar.
25	A process for the preparation of 4-[2-[[3-(4-hydroxyphenyl)-1-methylpropyl]amino]ethyl]-1,2-benzenediol: Indian Pat. **1082/MUM/2006** (provisional filed on July 10, 06) Ms. Mandakini Pillai, Ankur Mistry, Mr. Vijay Patel, Dr. Dr C Trinadha Rao and Dr T Rajamannar
26	Cyclodextrin complexes of Atovaquone: **Indian Pat. 833/MUM/2007** (provisional filed on Apr 27, 07): Mr. K. Sudhakar, Mr. T. Nathmani, Mr. T. Veerababu, , Dr. Dr C Trinadha Rao and Dr T Rajamannar.
27	Process for the preparation of (1*S*,4*S*)-4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-*N*-methyl-1-naphthylamine hydrochloride: **Indian Pat. 1279/MUM/2007** (filed on June 04, 07): Mr. Rutvij Bhatt, Mr. K. Bhorkataria, Dr. K. J. Jadav, Dr C Trinadha Rao and Dr T Rajamannar
28	Substantially pure amorphous form of (11β,16α-16,17-[[(*R*)-cyclohexylmethylene]bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-diene-3,20-dione: **Indian Pat. 2185/MUM/2007** (provisional filed on November, 02, 2007); Dr. J. Patel, Mr. G. Sheth, Mr. G.C. Patel, Dr C Trinadha Rao and Dr T Rajamannar
29	Stable amorphous form of 3-(*S*)-(+)-(1-carbamoyl-1,1-diphenylmethyl)-1-[2-(2,3-dihydrobenzofuran-5-yl) ethyl]pyrrolidine hydrobromide **Indian Pat. 2251/MUM/2007** (provisional filed on November 14, 2007); Mr. Rajesh L Giri, Mr. K. Sudhakar, Dr C Trinadha Rao and Dr T Rajamannar
30	Novel hydrazide containing tyrosine kinase inhibitors **Indian Pat. 160/MUM/2008** (provisional filed on January 23, 2008); Dr. P. Sengupta, Hemant Chokshi, Dr C Trinadha Rao and Dr T Rajamannar
31	Novel hydrazide containing taxane conjugates : **Indian Pat. 378/MUM/2008.** (provisional filed on February 21, 08); Dr. J. Patel, Mr. G. Sheth, Mr. G.C. Patel, Dr C Trinadha Rao and Dr T Rajamannar
32	Novel crystal form of (5-methyl-2-oxo-1,3-dioxolen-4-yl)methyl 4-(1-hydroxy-1-methylethyl)-2-propyl-1-[4-[2-(tetrazol-5-yl)phenyl]phenyl]methylimidazole-5-carboxylate; **Indian Pat. 843/MUM/2008.** (provisional filed on April 11, 08); Ms. Komal B Jethwa, Mr. K. Sudhakar, Dr C Trinadha Rao and Dr T Rajamannar